K022740

NOV 1 4 2002

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

August 16, 2002

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software

COMMON NAME:

Patient Monitor

CLASSIFICATION NAME:

The following Class III classification appears applicable:

DSI	Arrhythmia detector & alarm	870.1025
MLD	Monitor ST-segment & alarm	870.1025

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software (S/5™ CCCM) is substantially equivalent in safety and effectiveness to the legally marketed predicate Datex-Ohmeda S/5™ Compact Critical Care Monitor with S-00C03, S-00C04 software (K002158).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The S/5™ Compact Critical Care Monitor is a patient monitor, which displays the measurement of patient physiological parameters in the hospital setting. The measurement of patient physiological parameters is accomplished by specialized measurement modules which, when plugged into the frame, allow the modules to communicate with the monitor.The caregiver can select from a variety of available measurements (parameters) and apply those parameters that are best suited to patient care. Modules perform the functions of parameter measurement and minor data processing. The S/5™ Compact Critical Care Monitor displays parameters on screen, signals alarms and performs advanced data processing. There are two software options available for the S/5™ Compact Critical Care Monitor: L-CICU02 and L-CICU02A. L-CICU02A is equipped with extended arrhythmia analysis capability. Other than arrhythmia analysis capabilities, this software option is identical to L-CICU02.

The modifications to the device are:

1. Technical alarms such as "SpO2 probe off", "Leads off" (ECG), and "Px No transducer" (InvBP) transferred to the Central Station.
2. Changed to include support for alarm silencing and alarm limits adjustment from Central Station.
3. The alarm priority of "X module removed" message has been increased from note level to yellow level.
4. Software can additionally send request for recording to Central Station.
5. Snapshot printing speed 25 mm/s has been added.
6. Rotating of the "ComWheel" now scrolls through different trend pages.
7. Standby information is additionally sent to Central Station.
8. Mean Arterial Pressure value replaces O2 FI value in vital parameters numerical trend.
9. The NMT cycle time selections have been changed to be:
   20 s / 1 min / 5 min / 15 min / 30 min / 60 min / 120 min.
10. Lifetime of an old NIBP value has been changed from 60 min to 245 min.
11. Support for M-BIS (Bispectral Index) module has been added.
    M-BIS has a separate 510(k)
12. Support for the M-MINIC (CO2 module) module has been added.
    The Mini CO2 module M-miniC is the subject of a separate 510(k) premarket notification.
13. Support for the N-DIS external device interfacing modules has been added. Support is for interfacing the following device categories: ventilators/anesthesia machines, stand-alone monitors, blood gas analyzers and heart-lung machines.
    The N-DIS modules have a separate 510(k) premarket notification.
14. Support for wireless LAN communication between the monitor and Datex-Ohmeda S/5 Central station.

The S/5™ CCCM uses several types of plug-in measurement modules.
Modules are the subject of separate 510(k)'s and are not part of this notification.
The S/5™ CCCM is typically furnished with a module that measures ECG, invasive and non-invasive blood pressures, pulse oximetry and temperature.
Modules are placed in the S/5™ Compact Monitor frame and are automatically recognized by the monitor. The patient cables are connected to the module plug in jacks and then monitoring can

begin. The S/5™ CCCM can display measurements in the form of numeric values, traces and trends. Audible and visual alarms are used to indicate patient status. The priority profile of an alarm depends on the parameter. The S/5™ CCCM is operated by a keyboard. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then be made easily from the menu using a unique ergonomically designed pointing device on the keyboard called a ComWheel™. The software L-CICU02 and L-CICU02A perform some module-related tasks like arrhythmia analysis, ST–value calculation, heart rate calculation, impedance and respiration rate calculation, energy expenditure calculation, EEG spectrum analysis and evoked potential response averaging. All the module communication is also handled in the main software.
There are various optional types of keyboards, some are like standard keyboards and another is a hand-held Remote controller (REMCO) which is still directly connected to the S/5™ Compact Critical Care Monitor via a long cord but provides more flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. The S/5™ Compact Critical Care Monitor can be in a stand-alone or networked configuration. If networked, measurement data is sent to the network for central station or monitor-to-monitor viewing. Trends can be sent via a network to a central computer for archiving.

INTENDED USE as required by 807.92(a)(5)

Intended use:

The S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A is intended for multiparameter patient monitoring.

Indications for use:
The S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), and neurophysiological status of all hospital patients. The S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents*. (*Gan TJ, Glass P, Windsor A, Payne F, Rosow C, Sebel P, Manberg P. Bispectral Index Monitoring Allows Faster Emergence and Improved Recovery from Propofol, Alfentanil and Nitrous Oxide Anesthesia. Anesthesiology, October 1997; (4) 87:808-15.)
The S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software (S/5™ CCCM) is substantially equivalent to the predicate Datex-Ohmeda S/5™ Compact Critical Care Monitor with S-00C03, S-00C04 software (K002158).
The S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), and neurophysiological status of all hospital patients. The S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents*.
(*Gan TJ, Glass P, Windsor A, Payne F, Rosow C, Sebel P, Manberg P. Bispectral Index Monitoring Allows Faster Emergence and Improved Recovery from Propofol, Alfentanil and Nitrous Oxide Anesthesia. Anesthesiology, October 1997; (4) 87:808-15.)

There are two software options available for S/5™ Compact Critical Care Monitor: L-CICU02 and L-CICU02A (collectively referred to as L-CICU02(A)). (Note: L- refers to software license). Only one software can be used at any given time in the monitor. The software is preloaded in the factory and can also be later loaded in the customer site. The new device with different software options S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A, is compared to predicates as outlined below.
The basic model of the monitor is S/5™ Compact Critical Care Monitor with L-CICU02, which is a new revision of the predicate devices, S/5™ Compact Critical Care Monitor with S-00C03 software (K002158). The S/5™ Compact Critical Care Monitor with L-CICU02 may be equipped with extended bedside arrhythmia analysis capability and in this case the monitor is called S/5™ Compact Critical Care Monitor with L-CICU02A. The arrhythmia analysis functionality of S/5™ Compact Critical Care Monitor with L-CICU02A is substantially equivalent to the functionality of the predicate device
S/5™ Compact Critical Care Monitor with L-00C04. The S/5™ CCCM is a modular multiparameter patient monitor providing connections to measurement modules. The general construction, indications for use and intended use of the S/5™ CCCM are the same as for the predicate S/5™ Compact Critical Care Monitor with S-00C03, S-00C04 software (K002158).Based on the above and a detailed analysis in Tab 4 Comparison and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software is substantially equivalent to the predicate S/5™ Compact Critical Care with S-00C03, S-00C04 software (K002158).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Compact Critical Care monitor with L-CICU02 and L-CICU02A software complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1995/EN 60601-2-30:1995
- IEC 60601-2-34:1994/EN 60601-2-34:1994
- IEC 60601-2-40:1998
- IEC 60601-1-2(1993)/EN 60601-1-2
- IEC 60601-1-4: 1996+Amdt. 1:1999/EN 60601-1-4
- ISO 9918:1993/EN 864:1996
- ISO 9919:1992/EN865:1997
- ISO 7767:1997/EN12598:1999
- ISO 11196:1995 + Corr. 1:1997/EN ISO11196:1997
- IEC 601-2-10:1987/HD 395.2.10:1988 + Am.1:2000
- IEC 60601-2-26:1994/EN60601-2-26
- IEC 60068-2
- UL 2601-1:1997
- ANSI/AAMI ES-1:1993
- ANSI/AAMI EC57:1998
- FDA 21 CFR 898.12

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2002

Datex-Ohmeda
c/o Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Rd.
Needham, MA 02492

Re: K022740
Trade Name: Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software
Regulation Name: Arrhythmia Detector and Alarm
Regulation Number: 21 CFR 870.1025
Regulatory Class: Class III (three)
Product Code: MLD
Dated: August 17, 2002
Received: August 19, 2002

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

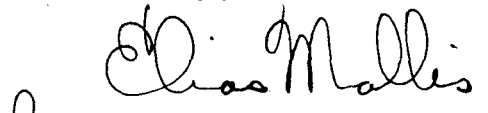
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022740

Device Name: Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software

Indications For Use:

The S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), and neurophysiological status of all hospital patients.

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The S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Elias Mallis

Division of Cardiovascular & Respiratory Devices
510(k) Number K022740